

memoranda applicable thereto, or in any other manner.

It is further ordered, That the respondents herein shall, within sixty (60) days after service upon them of this order, file with the Commission a report in writing setting forth in detail the manner and form in which they have complied with this order.

IN THE MATTER OF
CHAS. PFIZER & CO., INC.

ORDER, OPINION, ETC., IN REGARD TO THE ALLEGED VIOLATION OF THE
FEDERAL TRADE COMMISSION ACT

Docket 7780. Complaint, Feb. 11, 1960—Decision, Oct. 16, 1964

Order dismissing without adjudicating the allegations—the Food and Drug Administration having asserted jurisdiction under the 1962 amendments of the Federal Food, Drug and Cosmetic Act, enacted during pendency of the proceeding—complaint charging a drug manufacturer with representing falsely in advertising mailed to doctors and inserted in medical journals that its product “Enarax” had been clinically tested for more than a year before it was placed on the market, that it had been tested on 512 patients, and that all the “references” listed therein related to the product when in fact they related to only one of its components.

COMPLAINT

Pursuant to the provisions of the Federal Trade Commission Act, and by virtue of the authority vested in it by said Act, the Federal Trade Commission, having reason to believe that Chas. Pfizer & Co., Inc., a corporation, hereinafter referred to as respondent, has violated the provisions of said Act, and it appearing to the Commission that a proceeding by it in respect thereof would be in the public interest, hereby issues its complaint stating its charges in that respect as follows:

PARAGRAPH 1. Respondent Chas. Pfizer & Co., Inc., is a corporation organized, existing and doing business under and by virtue of the laws of the State of Delaware, with its principal office and place of business located at 11 Bartlett Street, Brooklyn, New York.

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PAR. 2. Respondent is now, and for some time last past has been, engaged in the manufacture, advertising, offering for sale, sale and distribution of a drug preparation called "Enarax," which preparation contains ingredients which come within the classification of drugs, as the term "drug" is defined in the Federal Trade Commission Act, to pharmacists for resale to the public.

PAR. 3. In the course and conduct of its business, respondent now causes, and for some time last past has caused, its said "Enarax," when sold, to be shipped from its place of business in the State of New York to purchasers thereof located in various other States of the United States and in the District of Columbia, and maintains, and at all times mentioned herein has maintained, a substantial course of trade in said product in commerce, as "commerce" is defined in the Federal Trade Commission Act.

PAR. 4. In the course and conduct of its business, respondent has disseminated, and caused the dissemination of, certain advertisements concerning the said preparation by the United States mails and by various means in commerce, as "commerce" is defined in the Federal Trade Commission Act, including advertising material mailed to individual members of the medical profession throughout the United States and advertisements inserted in various medical journals having national circulation, for the purpose of inducing, and which were likely to induce, directly or indirectly, the purchase of said preparation; and has disseminated, and caused the dissemination of, advertisements concerning said preparation by various means, including the aforesaid media, for the purpose of inducing, and which were likely to induce, directly or indirectly, the purchase of said preparation in commerce, as "commerce" is defined in the Federal Trade Commission Act.

PAR. 5. Respondent, by means of the aforesaid advertisements and advertising material, has represented, directly or by implication, that the product "Enarax" had been clinically tested for more than a year before it was placed on the market; that it had been tested on 512 patients; and that all of the "references" listed therein related to said product.

PAR. 6. The aforesaid advertisements and representations contained therein are misleading in material respects and constitute "false advertisements" as that term is defined in the Federal Trade Commission Act. In truth and in fact, the product "Enarax" had not been clinically tested for more than a year. It had not been tested on 512 patients. Many of the "references" listed in respondent's advertising material

did not relate to the product "Enarax," but instead related to only one of the components of "Enarax".

PAR. 7. The dissemination by the respondent of the false advertisements, as aforesaid, constituted unfair and deceptive acts and practices in commerce, within the intent and meaning of the Federal Trade Commission Act.

Mr. Edward F. Downs and *Mr. Anthony J. Kennedy, Jr.* supporting the complaint.

Dewey, Ballantine, Bushby, Palmer & Wood, by *Mr. John E. F. Wood*, *Mr. Charles E. Stewart, Jr.*, *Mr. Arnold G. Fraiman* and *Mr. Judson A. Parsons, Jr.* for the respondent.

INITIAL DECISION BY HARRY R. HINKES, HEARING EXAMINER

AUGUST 8, 1962

The complaint in this matter charges the respondent, Chas. Pfizer & Co., Inc., a corporation, with violation of the Federal Trade Commission Act in the dissemination of certain advertisements concerning a drug preparation. Following respondent's answer denying violations of the Act, hearings were held, at which the testimony of medical practitioners was received and a number of exhibits admitted in evidence. Proposed findings and briefs have been filed by both parties. To the extent they are inconsistent with the findings made herein, they are deemed rejected.

On the record thus constituted, the undersigned makes the following:

FINDINGS OF FACT

1. Respondent Chas. Pfizer & Co., Inc., hereafter sometimes referred to as Pfizer, is a corporation organized, existing, and doing business under and by virtue of the laws of the State of Delaware, with its principal office and place of business located at 11 Bartlett Street, Brooklyn, New York.

2. Respondent is now, and for some time last past has been, engaged in the manufacture, advertising, offering for sale, sale, and distribution of a drug preparation called Enarax, which preparation contains ingredients which come within the classification of drugs, as the term "drug" is defined in the Federal Trade Commission Act, to retail drug outlets and others. In certain cases Pfizer's customers resell such products and preparations to the public.

3. Federal law prohibits the sale of Enarax to the public except on the prescription of a physician.

4. In the course and conduct of its business respondent now causes, and for some time last past has caused, its Enarax, when sold, to be shipped from its place of business in the State of New York to purchasers thereof located in various other states of the United States and in the District of Columbia, and maintains, and at all times mentioned herein has maintained, a substantial course of trade in said products in commerce, as "commerce" is defined in the Federal Trade Commission Act.

5. In the course and conduct of its business, respondent has disseminated, and caused the dissemination of, certain advertisements concerning the said preparation by the United States mails and by various means in commerce, as "commerce" is defined in the Federal Trade Commission Act. This advertising material was mailed only to individual members of the medical profession throughout the United States or inserted in various medical journals having national circulation, for the purpose of inducing, and which were likely to induce, directly or indirectly, the purchase of said preparation in commerce, as "commerce" is defined in the Federal Trade Commission Act.

6. Enarax is a drug preparation used principally in the treatment of peptic ulcers and other gastrointestinal disorders. Enarax contains two components, namely, an anticholinergic agent, oxyphenacyclimine, sold under respondent's tradename of Daricon, and a tranquilizer, hydroxyzine hydrochloride, sold under respondent's tradename of Atarax. Each of the components of Enarax has its own therapeutic properties.

7. No question has been raised as to the efficacy and safety of Enarax. There is no contention that in marketing and advertising Enarax respondent has made any claims or representations with respect to its safety or efficacy which are not in fact true.

8. Oxyphenacyclimine, the anticholinergic component of Enarax and the more important component of the combination, was developed by respondent. After extensive and thorough clinical testing, which had been reviewed by the Food and Drug Administration, and after a New Drug Application pertaining to it had been made effective, it was separately marketed by respondent in January 1959. It is similar in its action to other anticholinergic agents marketed by other pharmaceutical houses.

9. Atarax, the tranquilizer component of Enarax, was first marketed by respondent as a separate drug in May 1956, and by 1959 was well known and widely used by the medical profession. Before Atarax was marketed, it had been subjected to an extensive and

thorough clinical testing program which had been reviewed by the Food and Drug Administration; and a New Drug Application pertaining to it had become effective.

10. Enarax was first marketed and advertised by respondent in March of 1959 after certain clinical tests of Enarax and of its components had been reviewed by the Food and Drug Administration and after a New Drug Application pertaining to it had become effective.

11. By the time Enarax was placed on the market, the medical profession had for many years been using combined anticholinergic and tranquilizer therapy in the treatment of the conditions for which Enarax is used. It was also well understood by the medical profession that, when anticholinergics and tranquilizers are used together, both act in exactly the same manner as if each drug were used alone. This is true whether they are administered separately but concurrently, or are combined in a single tablet.

12. In respondent's advertisements appearing in the medical journals as well as in the literature distributed to the medical profession, which were the only advertisements of the drug, truthful disclosure was made of the formula of Enarax, showing quantitatively each of its ingredients.

13. Typical of the advertisements circulated by respondent on Enarax were the following:*

14. Respondent, by means of the aforesaid advertisements and advertising material, has represented directly or by implication that Enarax had been clinically tested for more than a year before it was placed on the market; that it had been tested on 512 patients; and that some of the footnote "references" listed therein related to the product Enarax.

15. In truth and in fact, Enarax had not been clinically tested for more than a year before it was placed on the market, nor upon 512 patients, and not all of the footnote references purportedly relating to Enarax did so relate. When placed on the market in March 1959, Enarax had been tested on only approximately 155 patients and some of the references purportedly relating to Enarax in fact related to one of the components of Enarax.

16. Before Enarax was marketed, a combination of oxyphencyclimine and Atarax, administered separately but concurrently, had been clinically tested for more than one year. In addition, oxyphencyclimine itself had been clinically tested on more than 512 patients and for more

*Pictorial advertisements are omitted in printing.

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than one year. Atarax had been clinically tested in over a thousand cases and had been on the market for almost three years when Enarax was first marketed.

17. By representing that Enarax had been clinically tested for more than a year in a given number of cases and found to be effective in a given number of cases, respondent necessarily represented that such clinical testing was properly conducted and adequate to establish the efficacy of Enarax as a treatment of the disorders for which it was recommended. Enarax was clinically tested according to 131 case reports submitted to the respondent by eight different doctors of medicine as well as 24 additional observations which are not on record here. The 131 case reports, when considered in connection with the other testing referred to in Finding 16, above, provided information sufficient in all respects for evaluating the safety and efficacy of Enarax, and constituted valid clinical testing.

18. There is no evidence in this record that the representation that Enarax had been clinically tested on 512 patients and for more than one year constitutes a false representation of a material fact in the light of the testing previously done upon the component ingredients of Enarax.

19. There is no evidence in this record that the footnote references erroneously attributable to Enarax instead of one of the component drugs constitute a false representation of a material fact.

DISCUSSION

The Food and Drug Administration has the duty of determining the adequacy of clinical tests before releasing a new drug on the market, and made such a determination for not only Daricon and Atarax, but for Enarax as well. The proceeding here at the Federal Trade Commission is directed only to the respondent's advertising.

Section 12 of the Federal Trade Commission Act makes it unlawful to disseminate any false advertisement for the purpose of inducing, or which is likely to induce, the purchase in commerce of a drug. Since drug is defined as an article intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man, it is clear that Enarax is covered thereby. The Act, further, defines a false advertisement and states:

* * * No advertisement of a drug shall be deemed to be false if it is disseminated only to members of the medical profession, contains no false representation of a material fact, and includes, or is accompanied in each instance by truthful disclosure of, the formula showing quantitatively each ingredient of such drug.

It is undisputed that the advertisements involved were disseminated only to members of the medical profession and included a truthful disclosure of the formula. The only issue, therefore, is whether these advertisements contained false representations of material facts.

Respondent first contends that these advertisements did not represent that Enarax had been clinically tested for more than one year and upon 512 patients, but, instead, represented that the tests were done on the anticholinergic component, oxyphencyclimine. If this were so, the issue could be resolved quickly in favor of the respondent since it is undisputed that oxyphencyclimine was so tested. However, the record makes it quite clear that some doctors would and did read these advertisements as representing that Enarax had been so tested rather than oxyphencyclimine. True, some of these doctors admitted that with more careful reading it would be clear that the testing referred to the oxyphencyclimine rather than to the Enarax. It is also true that doctors should render a more than superficial reading of a medical advertisement. Nevertheless, we are not concerned with what a doctor should do, but with what a doctor does. It is inescapable to conclude that some and perhaps many doctors will read these advertisements superficially and come to the conclusion that Enarax had been tested for more than one year and on 512 patients. The representation thus conveyed to the unsuspecting doctor is false even though some doctors making a careful reading of the advertisement and with specialized knowledge of the subject would not be misled.

This conclusion, however, does not dispose of this case. It is not sufficient to find that a representation in a drug advertisement is false. False representation, as the Act clearly spells out, must involve a material fact before it may be concluded that there was a false advertisement. The issue here is whether a representation that Enarax had been clinically tested when, instead, only its component ingredients had so been tested is a false representation of a material fact. Stated otherwise, does it matter materially if a doctor reading the Enarax advertisement thinks that Enarax, rather than its components, had been clinically tested? On this issue I am compelled to conclude that Commission counsel have not sustained the burden of proof incumbent upon them.

Counsel supporting the complaint called six medical practitioners. One, Dr. Karp, testified that he would prescribe Enarax whether it had been clinically tested or not because he was familiar with the component drugs involved and knew that they had been tested. Another, Dr. Fine, was an eye, ear, nose, and throat specialist who does not use anticholinergics in his practice so there would be no basis for deter-

mining what difference it made to him whether these component drugs had been tested or not. Drs. Sisskind and Saeli were not asked whether it mattered to them that Enarax had not been tested as advertised. Dr. Brozen testified that he liked to know what a new product consisted of. Finally, Dr. Grollman, who testified at great length on the validity of the clinical tests, was silent as to what difference it made to him or the medical profession that Enarax had not been tested as advertised, but only its components.

On the other hand, all the doctors called by the respondent testified that it made no difference whether Enarax had been clinically tested or not since the two component drugs of Enarax had been clinically tested and the action of the components, as well as the combined drug, was known. One of them, Dr. Ruffin, explained further that, although a physician is very hesitant to prescribe a new drug that has never been tested, he would be just as well satisfied to know only that the components of the mixture had been tested and not the mixture itself. Moreover, even if a physician did not know the action of the individual component drugs of a mixture, but knew there had been clinical testing of such component drugs, he would be satisfied in using the untested combination. He also stated:

Q. So that if you look at the two components and you mix them together and there is no change in the chemistry of the two, then, in your opinion, there is no necessity to test the combination?

A. Absolutely none, as far as I am concerned.

Q. Well, as far as you are concerned but how about as far as the medical profession is concerned?

A. Well, if I can speak for the profession, the answer is there is no occasion for the testing.

Q. That is in all instances?

A. Yes, sir, and I can find you dozens of instances in which this is accepted by the profession.

The testimony of each of the three gastroenterological specialists called by the respondent is essentially the same. There is nothing in the record which suggests that any doctor would consider these advertisements to be false representations of a material fact in conveying the impression that Enarax had been clinically tested for more than one year and on 512 patients, when, as a matter of fact, it had not been so tested, but only its component drugs had been. Counsel supporting the complaint urge that the hearing examiner, nevertheless, conclude that such misrepresentation involved a material fact and ignore the testimony of the medical specialists to the contrary. Such action on my part, I believe, would be unwarranted and presumptuous. The field of chemistry and medicine is a highly technical area where even experts often

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disagree. To conclude, in the absence of any supporting data, that something is a material fact to the medical profession where the record contains only a flat contradiction by the medical experts to such conclusions is the height of folly. Indeed, it would be difficult to render a decision if there were contradictory versions by the specialists. Here, however, all the evidence points in one direction. I cannot set myself up as an authority to take official notice of scientific complexities at variance with uncontradicted expert opinion. These are not "material facts * * * within [the] expert knowledge [of the Commission] derived from experience." Even if they were such, respondent had the right "to show the contrary" (Administrative Procedure Act, Sec. 7(d), 5 U.S.C. 1006(d)) which it did here. See *Manco Watch Strap Co., Inc.*, Docket No. 7785, March 13, 1962 [60 F.T.C. 495]; cf. *Industrial Engineering Associates*, 50 F.T.C. 300 (1953) where the Commission upheld of the hearing examiner who found:

* * * since the representation * * * was * * * made in a publication intended for circulation among physicians only, who, it can be assumed, will not be misled by anything respondents might say regarding their product, and since there is no substantial evidence that the general consuming public would be misled thereby, * * * public interest does not require * * * corrective action * * *. (Emphasis supplied.)

Also, *Waltham Precision Instrument Co., Inc.*, Docket No. 6914, July 20, 1962 [61 F.T.C. 1027], where no deception was found in the use of a term in an advertisement addressed to the watch-making trade which term was "not likely to confuse the technical experts * * *." (Emphasis supplied.)

Similarly, as regards the footnote references in these advertisements, it is undeniable that, although some of them were keyed to specific items in the advertisements, others were not so keyed and could be, and were, understood by some doctors to refer to Enarax, when as a matter of fact they referred to one of the component drugs. The impression left with some doctors reading the advertisement was undoubtedly misleading. The materiality of such misrepresentation, however, is entirely unknown. Some of the doctors testified that they would be interested in knowing more about the component drugs. The record, however, is silent as to what difference it made to them that a specific footnote referred to a component drug rather than to the combination, Enarax. As in the case of the clinical testing, I cannot substitute my impression and conclude that doctors receiving the advertisement would experience the same. Such proof was the burden of counsel supporting the complaint and its absence cannot be compensated for by official notice.

The conclusions reached above require a dismissal of this complaint and render it unnecessary to decide whether the 131 case reports on Enarax constituted valid clinical tests. Since, however, this issue was contested vigorously, some comment is warranted, particularly in view of the current concern regarding drug testing. Commission counsel presented Dr. Grollman who testified that the 131 reports were not adequate to constitute valid clinical testing. Respondent's witnesses, on the other hand, disagreed and testified that neither the lack of formal controls, nor the lack of underlying data upon which the diagnoses were based, nor the insufficiency of the progress notes, nor the absence of testing for side effects, nor the use of adjunctive therapy, rendered these clinical tests invalid. It appears from the record that the validity of a clinical test has various criteria, depending upon whether the drug is a life-saving drug, like an antibiotic; a drug with specific actions in specific diseases; or a drug for the relief of symptoms, like Enarax. In the clinical tests of the life-saving drug and the drug with a specific action, an evaluation of the drug's efficacy is accomplished by laboratory tests. In testing a drug used for symptomatic relief, it may be proper to make a subjective evaluation which cannot be demonstrated objectively. Under such circumstances, the inadequacies and insufficiencies objected to by Dr. Grollman were not critical, in the opinion of the gastroenterological experts, *particularly in view of the prior testing done upon the component drugs*. Although Dr. Grollman is a doctor of considerable repute, he has not had the degree of specialization in gastroenterology that the respondent's witnesses possess, nor does it appear he was made familiar with the prior clinical testing done upon the component drugs of Enarax. On balance, therefore, it is reasonable to conclude that, although valid clinical testing should often and perhaps usually have the controls and underlying data specified by Dr. Grollman, such completeness is not required in all types of clinical testing; that in the clinical testing of drugs for the relief of symptomatic disorders where the component drugs have been subjected to clinical testing, simpler and more abbreviated tests are valid for such purpose. The testing of Enarax falls within the latter category and constituted valid clinical testing in the unanimous expert opinion of the gastroenterological specialists who testified.

ORDER

It is ordered, That the complaint be, and the same hereby is, dismissed.

OPINION OF THE COMMISSION

OCTOBER 16, 1964

The Commission issued its complaint in the above-captioned proceeding in 1960. The complaint charges respondent with having misrepresented, in advertising material for its prescription drug "Enarax", that the product had been clinically tested for more than a year before it was placed on the market, and with related misrepresentations, in violation of Section 12 of the Federal Trade Commission Act, which proscribes false advertising of food, drugs, devices or cosmetics. While the matter was pending before the Commission on cross-appeals from the initial decision of the hearing examiner dismissing the complaint on the merits, the Federal Food, Drug, and Cosmetic Act was amended by the passage of the Drug Amendments of 1962. Subsequently, certain regulations were promulgated by the Secretary of Health, Education, and Welfare as provided for in the amendments.

On July 10, 1964 [p. 1521 herein], the Commission ordered "that the appeal in this case should be reargued, such reargument to be limited, however, to the following single question: whether the Drug Amendments of 1962 (76 Stat. 780) to the Federal Food, Drug and Cosmetic Act, and/or any regulations issued under such amendments by the Secretary of Health, Education, and Welfare cover the acts and practices alleged in the complaint." The order further provided that "the General Counsel of the Department of Health, Education and Welfare is invited to submit a brief setting forth the Department's views on the question presented and, if he desires, to participate in the oral argument." The matter having been duly reargued, and the views of the Department on the question having been received by the Commission in a letter of August 4, 1964, from the Assistant General Counsel for Food and Drugs, decision of the appeal is now appropriate.

Section 502(n) of the amended Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 352(n), provides that a prescription drug shall be deemed misbranded "unless the manufacturer * * * includes in all advertisements * * * such * * * information in brief summary relating to side effects, contraindications, and effectiveness as shall be required in regulations which shall be issued by the Secretary [of Health, Education, and Welfare]." Section 502(n) further provides that "no advertisement of a prescription drug, published after the effective date of regulations issued under this subsection applicable to advertisements of prescription drugs, shall, with respect to the matters specified in this subsection or covered by such regulations, be subject

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to the provisions of sections 52-57 of Title 15 [*i.e.*, Sections 12 through 17 of the Federal Trade Commission Act, as amended]". One of the regulations that the Secretary has promulgated pursuant to Section 502(n) provides that every prescription-drug advertisement "shall fairly show the effectiveness of the drug in the conditions for which it is recommended in the advertisement, together with a showing of those side effects and contraindications that are pertinent with respect to the uses recommended * * *. A fair balance shall be made in presenting the information on effectiveness and that on side effects and contraindications." 21 CFR § 1.105(e). The Department of Health, Education, and Welfare has advised the Commission that this provision of the regulations embraces the false advertising of Enarax charged in the Commission's complaint; in its letter of August 4, 1964, the Assistant General Counsel for Food and Drug states:

We do not regard an ad as complying with the "fair balance" requirements when it falsely represents the extent of the clinical testing as alleged in your complaint. We consider the advertising complained of in your Docket No. 7780 to be within the scope and application of the Amendments of 1962 of the Federal Food, Drug, and Cosmetic Act and the regulations promulgated thereunder.

Congress, in the Drug Amendments of 1962, desired to avoid both regulatory gaps and regulatory conflicts in the policing of prescription-drug advertising by the Federal Trade Commission and the Food and Drug Administration. Accordingly, since the FDA has asserted jurisdiction under Section 502(n) of the advertisements challenged in the Commission's complaint, the Commission will not proceed further in this matter, but will set aside the initial decision and dismiss the complaint without an adjudication of the allegations of the complaint. Should the FDA's assertion of jurisdiction subsequently prove unfounded, in part or in whole, the Commission will take such further action in this area as may be warranted in the public interest.

It should be noted that the Commission's complaint was brought exclusively under the food and drug sections (Sections 12 through 17) of the Federal Trade Commission Act. While Section 12 proscribes false advertising exclusive of labeling, Section 5 of the Federal Trade Commission Act proscribes all unfair or deceptive acts or practices in interstate commerce whether involving advertising or labeling. The Drug Amendments of 1962 were clearly not intended to repeal the Commission's authority under Section 5 to proceed, where appropriate to prevent any regulatory gap, against unfair or deceptive representations in the marketing of prescription drugs.

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FINAL ORDER

This matter having been heard by the Commission on cross-appeals from the initial decision of the hearing examiner dismissing the complaint, and the Commission having determined, for the reasons set forth in the accompanying opinion, that the initial decision should be set aside and the complaint dismissed without an adjudication of the allegations of the complaint,

It is ordered, That the initial decision be, and it hereby is, set aside.